

Claims

1. Process for the preparation of micro- and/or nanoparticles of a substance, characterized in that molecularly distributed substances are associated into particles and simultaneously stabilized in suspension, the substance being dissolved in solvent system for it and a non-solvent for this substance subsequently being added which is miscible with the solvent for this substance, one or more crystal growth inhibitor(s) being added and a rapid combining of solvent system and non-solvent being carried out, as a result of which the substance is precipitated with formation of a dispersion of particles which have a size in the micro or nanometer range.
2. Process according to claim 1, characterized in that the solvent system comprises one or more solvents for the substance.
3. Process according to claim 1 or 2, characterized in that the solvent system includes one or more solvents selected from aliphatic or aromatic alcohols, ketones, nitriles, in particular ethanol, methanol, isopropanol, acetone and/or acetonitrile.
4. Process according to one of the previous claims, characterized in that the substance in the non-solvent for this substance has a solubility less than 1g/100 ml, in particular less than 0.1 g/100 ml.
5. Process according to one of the previous claims, characterized in that the non-solvent includes one or more non-solvents selected from water, organic solvent with a hydrophilic character such as methanol.
6. Process according to one of the previous claims, characterized in that the substance is a water-soluble substance and the non-solvent or the mixture of several non-solvents is an organic solvent which is a non-solvent for the substance.

7. Process according to claim 6, characterized in that the non-solvent system of one or more non-solvents is selected from aliphatic or aromatic alcohols, ketones, nitriles, aldehydes or amides, in particular from linear or branched C₁-C₁₀ alcohols, preferably isopropanol, methanol or ethanol, C₃-C₁₀ ketones, preferably acetone, acetaldehyde, acetonitrile or dimethyl formamide.
8. Process according to one of the previous claims, characterized in that the crystal growth inhibitor(s) is/are selected from polyvinyl alcohols, cellulose ethers, cellulose esters, caseinates, casein, sodium alginate, polyvinyl alcohol-polyethylene glycol graft copolymers, polyvinyl pyrrolidone, povidone, PVP, hydroxyethyl starch, HES, polyacrylates/polymethacrylates, chitosan, agar, pectin, sugar, dextrans, gelatine A, gelatine B, gum arabic, poloxamers, ethoxylated triglycerides, sugar esters, sugar ethers, alkali soaps (fatty acid salts), ionic and zwitterionic surfactants, polysorbates, polyoxyethylene fatty alcohol ethers, polyoxyethylene fatty acid esters and phospholids or any mixtures of same, in particular those selected from the group of hydrophilic polymers.
9. Process according to one of the previous claims, characterized in that the crystal growth inhibitor(s) is/are a cellulose ether selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl methylcellulose, methyl cellulose and methylhydroxy ethylcellulose.
10. Process according to one of the previous claims, characterized in that the crystal growth inhibitor is hydroxypropyl methylcellulose.
11. Process according to one of the previous claims, characterized in that the concentration of crystal growth inhibitors relative to the substance to be precipitated is in the range from 0.01 to 50 wt.-%, preferably 0.1 to 30 wt.-% and preferably 0.5 to 20 wt.-%.

12. Process according to one of the previous claims, characterized in that the particles are present in crystalline form or amorphous form.
13. Process according to one of the previous claims, characterized in that the particles are present in crystalline or amorphous form and have a size of 100 μm to 10 nm, preferably 50 μm to 20 nm, in particular 30 μm to 30 nm and particularly preferably 15 μm to 100 nm.
14. Process according to one of the previous claims, characterized in that that the substance is an active ingredient.
15. Process according to one of the previous claims, characterized in that the substance is a pharmaceutical active ingredient.
16. Process according to one of the previous claims, characterized in that the dispersion is spray-dried or freeze-dried or dried by solvent evaporation or in that the powder is obtained by filtration techniques or in that a combination of a variety of these processes is used.
17. Process according to one of the previous claims, characterized in that the substance micronized according to this process is a substance or drug which has a low cohesivity, a low adhesivity and just an extremely low electrostatic charge.
18. Use of micro- and/or nanoparticles which have been prepared according to a process according to one of claims 1 to 17, for the production of colloidal dispersions.
19. Use of micro- and/or nanoparticles which have been prepared according to a process according to one of claims 1 to 17, for the preparation of drugs, preparations or administration forms which are solid, semi-solid, liquid or to be dispersed in air.

20. Use of micro- and/or nanoparticles which have been prepared according to a process according to one of claims 1 to 17, in drugs in order to increase the dissolution rate and thus the bioavailability of the active ingredient.
21. Use of micro- and/or nanoparticles which have been prepared according to a process according to one of claims 1 to 17, in drugs for parenteral use.
22. Use of micro- and/or nanoparticles which have been prepared according to a process according to one of claims 1 to 17, in drugs for pulmonary use in a powder inhaler with or without further adjuvants or supports.
23. Use of micro- and/or nanoparticles which have been prepared according to a process according to one of claims 1 to 17, in drugs for pulmonary use in a suspension aerosol (preparation in pressurized container), preferably no further adjuvants being used in addition to the propellant or propellant mixture.

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